CROSS- REFERENCE TO RELATED APPLICATIONS

" Not Applicable"

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT

" Not Applicable "

REFERENCE TO A MICROFICHE APPENDIX

" Not Applicable "

BACKGROUND OF THE INVENTION

new

This relates to the field of Orthopedics and Trauma, human, or veterinary. It may also have applications in plant biology and non-living mechanical materials.

Bone is living tissue. Bone fragments and surfaces can unite by biological activity over a length of time, given proper conditions to favor it. During this biological process of healing, the fragments have to be held together continuously by various means, to achieve a finally acceptable shape and length of the bone without deformity ,and of sufficient strength to restore function to the part.

The biological process is favored by the following measures.

1. Immobilization of the fragments or surfaces attempting union.

2. Compression of the surfaces to increase the rigidity of immobilization, and also promoting the biological process of direct union without excessive callus formation.

3. Relieving stress and recurrent injury to the soft-tissues and neuro-circulatory mechanisms by the immobilization.

4. Immobilizing only the healing parts, and to encourage movement and activity of un-injured parts.

entry approved. [illegible] 11/29/03

This has been attempted by the following methods.

A. Continuous traction.

B. External casts of Plaster of Paris, other casting material and braces.

C. Internal fixation.

D. External fixation.

E. Combined methods of fixation.

A. Continuous traction:

This can restore the length of the limb, and further measures can correct deformities like rotation and angulation to some extent.

The following problems of this method seldom make it the preferred treatment.

1. It is difficult to maintain the traction force continuously even with very frequent attention.

2. Patient cooperation is difficult to achieve.

3. Due to intermittent loss of traction force, mal-union may occur. Distraction and movement of fragments may cause delay or failure of union.

4. Circulatory problems can occur in the distal limb.

5. Wounds in the traction surface will not allow such a treatment.

B. External casts of Plaster of Paris, other casting material and braces.

The following problems are associated with them.

1. The immobilization is not rigid enough when it is critically essential.

2. Encircling of the part causes sweating and discomfort in hot climates.

3. Pressure sores can occur at pressure points, or due to insertion of hard objects by

patient for scratching. Bugs can get in.

4. Swelling of part within the cast can cause tightness and loss of circulation.

5. Loosening of cast occurs due to loss of swelling of part, or due to moisture reducing the thickness of the padding, resulting in loss of reduction.

6. There is no access to any wounds inside which may need attention, except by cutting out windows or leaving the cast incomplete, which may jeopardize the immobilization, and fracture reduction.

7. Uninvolved parts also get immobilized, a setback to recovery.

Due to these factors it can suffice only when rigid immobilization is not critically important, and usually in the absence of complicating factors of wounds and circulation.

C. Internal fixation :-

This may be applied along the side of a bone in the form of a plate and screws of the preferred design. It allows accurate reduction when this is most desirable, a bone graft can be added, and lag screws may be added when feasible, for inter-fragmentary compression. Sliding devices can be added to passively close any gaps arising later.

Disadvantages are as under.

1. Large exposures are required with relatively greater damage to the soft-tissues and bone circulation. Meticulous technique may minimize this, yet exposure is larger.

2. Compression once applied at operation, wears off within hours depending on the quality of bone. There is no possibility of renewing this compression once the wound is closed over the device. It is not acceptable to re-anaesthetize and re-expose the device repeatedly to re- tighten the screws.

3. Newer minimally invasive methods are performed through smaller incisions but in order to place the plate directly on bone, the periostium and muscles have to be stripped blindly. Even so, the plate is always unavoidably placed over some soft-tissues which melt away by the pressure and loosen the plate within hours. Loss of torque of screws is unfavorable to bone biology.

4. Plates are seldom favored in compound fractures.

5. Fracture haematoma gets dispersed.

Internal fixation may be applied inside the medullary canal of bone in the form of nails, pins and wires.

In closed nailing the fracture haematoma is preserved.

The disadvantages are as under.

1. It is generally not applicable to children, due to growth plates at the ends of bones.

2. It invades and occupies the bone from end to end, with the possibility of spreading infection.

3. It is not stable to rotational forces, and interlocking methods are not available for all situations.

4. In open nailing, the fracture haematoma gets dispersed.

D. External fixation:

This is most ideally suited for open injuries of bone. The commonly used basic bone implant for the external fixator is the Schanz screw which can be inserted at a safe distance from the open wounds and fracture ends.

1. Access to the wounds for frequent attention is easy.

2. There is no aggravation of injury to bone or soft-tissue.

3. Safe corridor entries of screws prevent injury to neuro-vascular structures.

4. In transverse fracture patterns, some compression can be applied along the axis of the bone.

The following limitations remain:

1. The basic implant e.g. the Schanz screw has a tendency to loosen in bone, leading to instability, and tendency to infection. Radial preloading of the implant in bone improves the stability, by the technique of inserting a larger diameter screw in a suitably smaller diameter drill-hole.

2. The preload is only in one mode, viz. Radial.

3. After loosening, there is no way of regaining any degree of stability in the same position, before the onset of infection. If the loose screw had been initially placed in the ideal site, then any next site for re-positioning the screw will be less than ideal.

4. There is no lag screw effect of a Schanz screw, to exert inter-fragmentary compression. Inter-fragment compression greatly enhances the stability, as well as the biological process of union. Fragments can at the most be splinted across, but not drawn together and compressed as in the lag-screw mode, by the conventional Schanz screw.

E. Combined methods of fixation:

When any one method is inadequate to neutralize all the forces of muscular pull and gravity, another method is added onto the first. For example, in " mini- internal fixation" methods; one or two lag screws used to hold together some fragments, are supplemented

by an external fixator construct, or by traction.

Even with such a supplementation, the lag screws can fail, because by the blind stab-hole technique, there is always some interposition of soft-tissue between the screw-head and the bone surface. This soft tissue quickly undergoes pressure necrosis to loosen the compression by loss of torque. The only residual control then is the external fixator, which may not be adequate for joint fragments. The compression once lost cannot be regained.

SUMMARY OF THE INVENTION:

This invention aims to preserve and augment the function of the primary bone implant of the external fixator. This is by a design, which adds the effect of an axial preload on the thread in the bone, to the older technique of radial preloading the implant. This has an additional effect on the stability and durability of the screw. The third element of stability is the surface preload of the screw-head on the bone surface. This is independent of the function of the head co acting in exerting axial preload torque on the thread within the bone. These stabilizing qualities are also renewable, because the screw can be again tightened after the first insertion.

Further, there is the introduction of the "lag-screw" function in the same basic implant of external fixator which is in an improved and versatile form, applicable to all situations which arise in fracture care.

There is also the capability of renewed and prolonged inter-fragmentary compression by means of subsequent turning of the screw from outside, which is a new and major advantage to the biology of bone healing.

The major drawback of the conventional screw loosening is

corrected to a significant extent, by this triple pre-load mechanism.

All positive features of the older implants are retained.

This device can be used to supplement minimally invasive plate osteosynthesis with double advantage. The screw torque can be renewed to keep the plate firmly seated on bone. The same screws form a construct outside and prevent failure of implanted plate.

The claimed invention combines the beneficial aspects of internal as well as external fixation.

It has no novel disadvantages of any kind whatsoever and permits wound access, is applied through minimal incisions, does not damage soft-tissue as in the open reduction and internal fixation methods, does not invade the medullary canal length-wise, and is applicable to children.

BRIEF DESCRIPTION OF DRAWINGS

FIG 1 is a diagrammatic front elevation of the improved external fixation implant with lag screw capability.

FIG 2 is a cross section of the improved basic external fixation implant in bone, showing radial pre-stress.

FIG 3 is a front elevation of the improved basic external fixation implant driven in a single bone fragment, exerting radial pre-load, surface pre-load, and axial pre-load widely distributed over bone/implant interfaces. No lag screw capability is intended.

FIG 4 is a prior art two-piece internal fixation device applied to two fragments of a fractured femur, with sliding capability of screw within the plate barrel, in a coronal

plane view.

FIG 5 is a prior art external fixator attempting to hold two fragments of a fractured femur, in a coronal plane view.

FIG 6 is a coronal plane view of the two piece fracture of the femur, showing the improved lag screw compression device across the fracture into both fragments, and the improved basic external fixation implants holding the distal fragment only; all taking part in the external fixation construct through connecting clamps.

FIG 7 is a five piece fracture of the distal femur with five fracture interfaces, in which the improved basic external fixation implants are holding only one large proximal fragment; and five improved lag screw external fixation implants are holding all the five fragments as well as compressing the five fracture interfaces, all being parts of the external fixator construct with tubes and clamps.

3 FIG 8 shows a prior art device with flat base, of Taylor et al, in which by driving at near a right angle to the fracture surfaces, the device becomes inclined to the outer bone surface at about 45 degrees, with engagement on edge.

FIG 9 shows the improved invention external fixation lag screw, inserted at about right angles to fracture plane, and at about 45 degrees to the outer bone surface, with the spherical head making a concentric and broad contact and distributing load in the matching countersink in bone surface.

FIG 10 Is an oblique basal view showing magnification of the hollow dome shaped head and adjoining portions towards the ends, of the improved basic implant.

FIG 11 is an oblique basal view showing magnification of the hollow conical head and

adjoining rod towards both ends, of the improved basic implant.

FIG 12 is an axial section of bone from which the improved basic external fixation implant has been removed, leaving behind a protective ridge of bone around the drill <u>hole.</u>

DETAILED DESCRIPTION OF THE INVENTION

FIG 1 is one form of the improved lag screw implant. It comprises

1, being the tip at the first end, with self- cutting capability. Such a tip removes the need for using a bone tap for cutting the thread, and is expedient.

2, is the short- threaded section at the first end.

3, being the smooth screw shaft section, has no chance of catching either in the wall or the edge of the drill hole. This is to disallow any chance of friction, which may occur while attempting to lag by over- drilling a gliding hole, and then to expect a fully threaded screw to glide through it smoothly.

4, is the spherical head for engaging the outer fragment of bone, which is capable of exerting well distributed pressure in a matching countersunk area at the outer surface of bone. This pressure will be even and equally distributed no matter what angle the improved device subtends at the bone surface. The head may be integral with the rod as in the drawing, or may be mobile to slide along the rod, to be fixed in a desired position by means of a transverse screw in the head, which can be driven into one of a series of holes provided in the rod.

The head 4 co acts with the thread 2 to tension the implant and compress a sliding fragment onto a fragment in which the thread is engaged for turning.

5, is the unthreaded drive shaft, which serves for driving the device; as well as for being secured through a connecting clamp to the external fixation construct. It also serves for renewing any compression lost subsequently over time. Such a loss of torque can occur due to head engaging some soft tissue covering the bone surface; this tissue will undergo necrosis under pressure and melt away in some time. It can be due to absorption of the fracture surfaces, etc. The improved device can be momentarily loosened at the clamp, turned tighter, and secured again at the clamp. The head 4 will continue to sit snugly at the countersink.

6 is the second end, with the gripping means at the second end, shown as a milled surface in this drawing, but the same can be quick coupling, or faceted, to suit the gripping handle or chuck.

7, is the guide-wire passing through the central canal running lengthwise in the entire device, from first end 1 to the second end 6. Since a lag screw is most effective at about right angles to the fracture surface, direction is most important. The guide wire helps to find the optimum direction, without damage to the bone stock which will occur if the bulkier implant itself is used to make repeated drives in bone.

The lag screw is mainly effective in tension mode, along the axis of the screw. Other forces of gravity and muscle pull are to be neutralized by the main external construct. Due to this consideration, it is possible to overlook the fact that a lag screw driven with a self-cutting tip is somewhat less durable than a screw with a non-tapping tip driven after cutting the thread with a tap.

FIG 2 shows the cross-section 11 of a prior art Schanz screw half pin, driven into a drill

hole of a slightly smaller diameter creating a radial pre-load 8, which is within the tolerance of the bone tissue. A higher load will lead to micro-fractures in the walls of the drill-hole, with crumbling of bone and loosening of device. The same technique is also applicable to the improved implant, being beneficial to stability. The surrounding bone tissue is designated B.

FIG 3 shows one form of the improved basic external fixation implant, inserted in tubular bone B.

1 is the non-self cutting tip at the first end. It is driven only after a thread has been cut with a bone tap, which is in the interest of durability, since the implant has to withstand significant forces of muscle pull and gravity.

2 is the threaded portion from tip 1 to the intercalated head 4. The full thread ensures maximum interface area with the female thread in bone, to tension the imbedded portion of implant, generating the axial pre-load 10.

Radial pre-load 8 has already been created by prior art technique, of driving the device through a judiciously smaller diameter drill hole. Too small a drill hole will overload the walls of the hole with damage to bone structure and loosening of the implant.

4 is the truncated conical hollow head, apex towards the second end 6. It makes contact with bone surface of a single fragment B, through blunt podia 14, created by a wavy or beaded margin of the rim of head base.

The gaps between the podia allow surface blood supply and nutrition to reach the margins of the drill hole, and encourage a ridge of new bone to form around the drill hole.

This ridge is similar to that which forms around the sides of a bone plate, and strengthens

the bone at the time of implant removal.

The podia exert a surface pre-load 9 on bone surface, and co acting with the thread, tension the implant axially.

Lateral forces applied to the drive shaft 5 are transmitted through the hollow head 4 through the podia 14 to the outer surface of bone and largely bypass the drill hole/ implant interface.

The head of the improved basic implant being integral with the rod, there is no micro-movement between the implant components, transmitting cyclic stresses to the implant/bone interfaces.

For a superficial bone like the tibia, an improved basic implant with a squat hollow head is selected, which will find ready skin cover. For deeper bones like the femur, a longer conical hollow head will be found easier to extract, at the end of treatment.

All stress applied to the second end of implant are widely distributed at the surface, drill hole and thread interfaces.

The engagement surface 14 of head is in a plane at right angles to the long axis of the improved device, because it is mechanically most efficient to drive the basic device at right angles to the bone surface. The engagement plane then fully meets the bone surface with broad contact.

Since it is easy to direct a drill at right angles to bone surface, there is no need for a guide wire technique. This works out in favor of the required strength of a basic external fixator implant, by eliminating the need for a lengthwise central canal in the rod.

FIG 4 is a coronal view of femur with fracture F, giving rise to two bone fragments B and

B'. A prior art two-piece internal fixation device, a sliding hip screw, is holding the fracture reduced at F. X is the hip screw and Y is the barrel of the plate in which the screw slides out in case of absorption of fracture surfaces and shortening of bone.

The device can also be tensioned by means of a small screw Z in the outer end of the hip screw X, engaging the outer end of the barrel Y by means of a head.

6 The compression can soon wear off, with no possibility of renewal. Sliding of screw within barrel may fail due to jamming, because forces in the area are not along the axis XYZ to encourage such an event. S is the skin integument of the part.

FIG 5 is the same fracture of FIG 4 held with one type of prior art external fixator, using prior art Schanz screws P, secured to an external tube strut 13, by means of a series of clamps 12. Absence of any head engaging the fragment B' precludes lag screw compression of B and B'. Gap may already be present at the fracture site at the end of surgery, or may occur later, which is adverse to bone healing.

FIG 6 is the same fracture of FIG 4 and 5, treated with the claimed improved implants. The upper two are improved lag screw implants, compressing fragments B' and B, across the fracture F, at nearly right angles to the fracture plane.

The lower two are improved basic implants into a single fragment B', gripping the fragment more securely with wide stress distribution at implant/bone interfaces.

Clamps 12, to tube 13, connect all components.

10 In the event of loss of lag screw compression, the lag screws can be loosened one by one at the clamp, turned tighter, and secured again at the clamp.

Just in case there is loss of stability of the basic implant, the same also can be restored by

similar subsequent tightening.

Radial pre-load once lost is not renewable, but due to the improved design, the surface and axial-pre-loads are renewable. The latter two also do protect the radial pre-load, in the case of the improved basic implant.

Renewed and sustained compression of fracture surfaces, aided by a stable basic construct, lead to quick union and reduce the chances of loosening, infection, and failure to unite. Numbers 1 to 6 are implant parts as per FIG 1.

FIG 7 shows a femur with multiple fractures in its distal end, with two epiphyseal fragments B'' and B''' bearing joint surfaces, and three more fragments B, B' and B'''' extending from metaphysis to diaphysis of bone.

Two improved basic external fixator implants hold the upper large diaphyseal fragment B.

The lower five are improved lag screws, of which the lowest two are lagging the joint fragments B'' and B''' into compression, at nearly right angles to the fracture plane F''. The third lag screw from below lags three fragments B'''', B' and B'', across fracture lines F''' and F'.

Since these two adjoining fracture planes cannot be parallel, the device cannot be at right angles to both of them. Due to this the best angle of insertion is to be decided by the experience of the surgeon. While in this drawing the device seems nearly at right angles to the surface of the bone, most lag screws end up at various angles of inclination to the outer surface, in order to be at right angles to the fracture plane.

The fourth and the fifth improved lag screws from below are nearly at right angles to the

fracture planes F'''' and F, with spherical heads lodging in matching countersunk beds in bone surfaces of fragments B'''' and B, with wide contact.

The drawing is diagrammatic, in which all implants are shown in the same coronal plane. In practice, the construct can be made more creative in different planes, to accommodate the needs of the fracture and soft tissues.

6 FIG 8 is one type of prior art implant of Taylor et al. When inserted at right angles to the fracture plane F in bone fragments B and B', the device is at about 45 degrees to the outer bone surface. This has caused the engagement means 4 to stand on edge at 45 degrees to the bone surface. The engagement means of all the implants patented by Taylor et al have an engagement plane at right angles to the rod axis, which will give consistent incongruous engagement problems in actual use.

FIG 9 shows the claimed improved external fixator lag screw with spherical head 4 nesting snugly with wide concentric stress distribution in a matching countersunk area C in bone surface of fragment B.

At any other angle of insertion also, the head will have the same concentric load distribution, preventing crumbling of bone due to stress concentration.

FIG 10 is an oblique basal view of the hollow dome shaped head 4 with podia 14 formed by a wavy margin of the rim of the base, for making interrupted contact with bone surface.

2, is the fully threaded section from first end 1 to the head 4.

FIG 11 shows a conical hollow head with blunt beaded podia at the margin, for interrupted contact with bone surface.

Interrupted contact allows surface blood vessels and nutrition to reach under the head to the drill hole margins, which maintains the bone integrity and encourages a rim of new bone formation, in the manner of such new bone forming at the margins of a bone plate. FIG 12 is a section of bone across a drill hole left after removal of the improved basic external fixator device.

A rim of new bone is seen in the section around the drill hole D at the margin, to strengthen the bone at that weakness left by implant removal. This is due to the novel head design allowing nutrition of the drill hole margin, the surface cortex under the hollow head, and the outer third of the bone cortex in that small area.

A similar ridge of bone around a bone plate is not removed at the time of plate extraction, to retain the strength of bone by means of this natural phenomenon.

CLAIMS

13. an improved solid rod like basic half-pin implant for external fixator systems, intended for being driven at right angles to bone surface; comprising,

a first end, with a thread at said first end; and a second end, with a means for gripping;

an intercalated hollow dome shaped head with an open base or equatorial area, with convexity or apex away from the said first end, having a blunt rim at base for contact with bone surface, the contact being interrupted by the presence of a blunt wavy margin of the rim, the said head being integral to said rod to disallow any micro-movement between said rod and said head;

the device being fully threaded from said first end to said head; and